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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,581	06/05/2001	Gary M. Fader	BB-1339	6372

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Wilmington, DE 19898

EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/857,581	Applicant(s) FADER ET AL.	
	Examiner Delia M. Ramirez	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11-19, 26, 29-33 and 51-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11-19, 26, 29-33 and 51-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

Claims 1, 11-19, 26, 29-33, 51-69 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/25/2005 has been entered.

In view of the fact that claims 51-69 are dependent from claim 1, claims 51-69 are now rejoined for examination. Claims 1, 11-19, 26, 29-33, 51-69 are under consideration and are being examined herein.

Applicant's amendment of claims 1, 14, 51-69, cancellation of claims 3-4, amendments to the specification, and submission of a new sequence listing in a communication filed on 2/25/2005 is acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 2/25/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The specification is objected to as containing new matter. The amendment filed on 2/25/2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132

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states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the sequence listing discloses a different SEQ ID NO: 66 from that originally filed. The sequence listing as originally filed shows a Lys residue at position 295. SEQ ID NO: 66 as disclosed in the new sequence listing shows "Xaa" at position 295 (any amino acid). There is no support for any amino acid at position 295 of SEQ ID NO: 66. Applicant is required to cancel the new matter in the reply to this Office Action.

3. The specification is objected to for the following reasons. Page 42 of the specification discloses that SEQ ID NO: 66 can have a Thr or Ile residue at position 294. However, the sequence listing as originally filed shows that position 294 of SEQ ID NO: 66 contains an Ile residue. Therefore, position 294 cannot have any other residue. Appropriate correction is required.

4. The specification is objected to for the following reasons. The sequence listing shows SEQ ID NO: 66 as having an Ile residue at position 294. However, in page 59 of the new sequence listing under Misc_Feature, the <223> identifier for position 294 indicates that position 294 is "Xaa = Thr or Ile". Applicants are requested to make the appropriate amendments to the sequence listing without introducing new matter.

Claim Rejections - 35 USC § 112, Second Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16, 30-31, 51-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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7. Claim 16 is indefinite in the recitation of “eukaryotic cell of claim 13” because there is no antecedent basis for a eukaryotic cell in claim 13. For examination purposes, it will be assumed that the claim reads “eukaryotic cell of claim 15”. Correction is required.
8. Claims 30-31 are indefinite in the recitation of “the method of claim 26 wherein the eukaryotic cell” because there is no antecedent basis for a eukaryotic cell in claim 26. For examination purposes, it will be assumed that the claim reads “the method of claim 29 wherein the eukaryotic cell”. Correction is required.
9. Claims 51-68 are indefinite in the recitation of “Xaa₂₉₄ is Ile” as it is unclear how it further limits the claims. SEQ ID NO: 66 contains an Ile residue at position 294, therefore this position is already defined. For examination purposes, no patentable weight will be given to the term. Correction is required.
10. Claim 69 is indefinite in the recitation of “Xaa₂₉₄ is Thr” since position 294 of SEQ ID NO: 66 contains an Ile residue. For examination purposes, no patentable weight will be given to the term since position 294 is already defined (i.e. cannot have any other residue). Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1, 11-19, 26, 29-33, 51-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Claims 1, 11-19, 26, 29-33, 51-69 are directed to a polynucleotide encoding the polypeptide of SEQ ID NO: 66, host cells and vectors comprising said polynucleotide, and a method to alter the level of expression of the polypeptide of SEQ ID NO: 66. As indicated previously, the polypeptide of SEQ ID NO: 66 as shown in the new sequence listing shows that position 295 can have any amino acid residue. However, SEQ ID NO: 66 as originally filed shows a Lys residue at position 295. The Examiner has not been able to locate support for the new SEQ ID NO: 66 in the specification. Therefore, there is no indication that the polynucleotides, host cells, vectors and method claim were within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

13. Claims 51-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 51-69 are directed to a polynucleotide encoding the polypeptide of SEQ ID NO: 66 wherein specific variable positions within SEQ ID NO: 66 are defined, such as positions Xaa₂₉₂ and Xaa₂₉₃. While the Examiner is able to locate support for any amino acid at positions 292 and 293, the Examiner is unable to locate support for the specific recited amino acids, i.e. Glu, Gln, Asp, His. Therefore, there is no indication that polynucleotides encoding the polypeptide of SEQ ID NO: 66 wherein positions 292-293 contain the recited residues were within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

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Conclusion

14. No claim is in condition for allowance.

15. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.


16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 4, 2005


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
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